

## § 526.464c

### § 526.464c Cloxacillin sodium for intramammary infusion, sterile.

(a) *Specifications.* Each milliliter contains cloxacillin sodium equivalent to 20.0 milligrams of cloxacillin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.165 of this chapter.

(d) *Conditions of use. Lactating cows—*  
(1) *Amount.* 10 milliliters (one dose of 200 milligrams) per infected quarter.

(2) *Indications for use.* Treatment of mastitis in lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus*, nonpenicillinase-producing strains.

(3) *Limitations.* Administer after milking, cleaning, and disinfecting, and as early as possible after detection. Treatment should be repeated at 12-hour intervals for a total of three doses. Milk taken from treated animals within 48 hours (four milkings) after the latest treatment should not be used for food. Treated animals should not be slaughtered for food within 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995; 68 FR 44878, July 31, 2003]

### § 526.464d Cloxacillin sodium for intramammary infusion.

(a) *Specifications.* Each milliliter contains cloxacillin sodium equivalent 20.0 milligrams of cloxacillin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.165 of this chapter.

(d) *Conditions for use. Lactating cows—*  
(1) *Amount.* 10 milliliters (one dose of 200 milligrams) per infected quarter.

(2) *Indications for use.* Treatment of mastitis in lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus*, nonpenicillinase-producing strains.

(3) *Limitations.* Administer after milking, cleaning, and disinfecting, and as early as possible after detection. Treatment should be repeated at 12-hour intervals for a total of three doses. Milk taken from treated animals within 48 hours (4 milkings) after the latest treatment should not be used for

## 21 CFR Ch. I (4–1–05 Edition)

food. Treated animals should not be slaughtered for food within 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992, as amended at 60 FR 55660, Nov. 2, 1995]

### § 526.820 Erythromycin.

(a) *Specifications.* (1) Each 6-milliliter, single-dose, disposable syringe contains 300 milligrams of erythromycin (as the base), 0.45 milligram of butylated hydroxyanisole, and 0.45 milligram of butylated hydroxytoluene.

(2) Each 12-milliliter, single-dose, disposable syringe contains 600 milligrams of erythromycin (as the base), 0.90 milligram of butylated hydroxyanisole, and 0.90 milligram of butylated hydroxytoluene.

(3) The vehicle is triglyceride of saturated fatty acids from coconut oil.

(4) The drug may or may not be sterile.

(b) *Sponsor.* See No. 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount.* (i) Lactating cows: After milking, cleaning, and disinfecting, infuse contents of a single 6-milliliter syringe into each infected quarter; repeat procedure at 12-hour intervals for a maximum of 3 consecutive infusions.

(ii) Dry cows: After milking, cleaning, and disinfecting, infuse contents of a single 12-milliliter syringe into each infected quarter at the time of drying off.

(2) *Indications for use.* Treatment of mastitis due to *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis* in lactating or dry cows.

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours (3 milkings) after the latest treatment must not be used for food.

[47 FR 15772, Apr. 13, 1982, as amended at 66 FR 14074, Mar. 9, 2001; 68 FR 4915, Jan. 31, 2003]

### § 526.1130 Hetacillin potassium for intramammary infusion.

(a) *Specifications.* Each 10 milliliter syringe contains hetacillin potassium equivalent of 62.5 milligrams of ampicillin.

**Food and Drug Administration, HHS**

**§ 526.1696a**

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use. Lactating cows—*

(1) *Amount*. 10 milliliters of hetacillin potassium equivalent to 62.5 milligrams ampicillin into each infected quarter. Repeat at 24-hour intervals until a maximum of three treatments has been given.

(2) *Indications for use*. Treating acute, chronic, or subclinical bovine mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Staphylococcus aureus*, and *Escherichia coli*.

(3) *Limitations*. If definite improvement is not noted within 48 hours after treatment, the causal organism should be further investigated. Milk that has been taken from animals during treatment and for 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food until 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 37335, Aug. 18, 1992]

**§ 526.1590 Novobiocin oil suspension.**

(a)(1) *Specifications*. Each 10 milliliters of oil suspension contains the equivalent of 400 milligrams of novobiocin (present as sodium novobiocin).

(2) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.460 of this chapter.

(4) *Conditions of use—(i) Amount*. Ten milliliters (equivalent to 400 milligrams of novobiocin) infused in each quarter.

(ii) *Indications for use*. It is used in dry cows for the treatment of mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae*.

(iii) *Limitations*. Infuse each quarter at the time of drying off, but not less than 30 days prior to calving. Do not slaughter treated animals for food use for 30 days following udder infusion. For udder installation for the treatment of mastitis in dry cows only.

(b)(1) *Specifications*. Each 10 milliliters of oil suspension contains the equivalent of 150 milligrams of

novobiocin (present as sodium novobiocin).

(2) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(3) *Related tolerances*. See § 556.460 of this chapter.

(4) *Conditions of use—(i) Amount*. Infuse 10 milliliters (equivalent to 150 milligrams of novobiocin) in each quarter after milking. Repeat treatment once after 24 hours.

(ii) *Indications for use*. Use in lactating cows for treatment of mastitis caused by susceptible strains of *Staphylococcus aureus*.

(iii) *Limitations*. Do not milk for at least 6 hours after treatment; afterwards, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after latest treatment must not be used for food. Do not slaughter treated animals for food for 15 days following latest treatment. If redness, swelling, or abnormal milk persists or increases after treatment, discontinue use and consult a veterinarian. For udder instillation in lactating cattle only. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[43 FR 10554, Mar. 14, 1978]

**§ 526.1696 Penicillin intramammary dosage forms.**

**§ 526.1696a Penicillin G procaine in oil.**

(a) *Specifications*. Each milliliter contains penicillin G procaine equivalent to 100,000 units of penicillin G in peanut, sesame, or soybean oils.

(b) *Related tolerances*. See § 556.510 of this chapter.

(c) *Sponsor*. See No. 010515 in § 510.600(c) of this chapter.

(1) *National Academy of Sciences/National Research Council (NAS/NRC) status*. The conditions specified in paragraph (c)(2)(i)(B) of this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

(2) *Conditions of use*. Treating bovine mastitis caused by *Streptococcus agalactiae*, *S. dysgalactiae*, and *S. uberis* in lactating cows as follows: